



AUG 24 1999

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Washington, D.C. 20231

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,041,126

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,041,126, which claims the medical device Cook GRIITM Coronary Stent, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 340 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 340 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 7, 1998 (63 Fed. Reg. 42408). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (343) + 168 \\ &= 340 \text{ days}\end{aligned}$$

Since the regulatory review period began December 20, 1995, after the patent issue date (August 20, 1991), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,041,126
Granted	:	August 20, 1991

Original Expiration Date : March 13, 2007
Applicant : Cesare Gianturco
Owner of Record : Cook Incorporated
Title : Endovascular Stent and Delivery System
Classification : 606/195
Product Trade Name : Cook GRIIT™ Coronary Stent
Term Extended : 340 days
Expiration Date of Extension : February 16, 2008

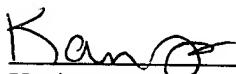
Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson

Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
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RE: Cook GRIIT™ Coronary Stent
FDA Docket No.: 97E-0461